

Remarks:

The specification and claims have been amended to make editorial changes to correct what, on their face, appear to be translation informalities and to more accurately reflect Applicants' invention. No new matter has been introduced. Page and line references here are referring to the published Patent Cooperation Treaty document WO 2004/044247 A2 published 27 May 2004. Also inserted are the corresponding paragraph numbers "[]" from Patent Application Publication US2006/0257871.

Basis for the above claim amendments is as follows:

Claim 1

The preamble of Claim 1 has been amended to relate to a method only. Basis can be found on page 4, lines 1-3, and in the preamble of Claim 1 as filed. The amendment removing "and kit" is without prejudice to Applicants' right to seek kit claim coverage elsewhere.

Step (a) has been revised to "providing" a sample to be tested or which is suspected of containing bacteria or fungus-yeast RNA. Basis can be found, for example, on page 4, lines 14-15. This amendment is merely clarifying, and adapts the claim to U.S. claiming practice.

Amended step (b) relates to polynucleotide primers *per se* (rather than to primers of specific sequences selected from "Preferred..." primers of page 5, line 8 ([0018])). Basis for this amendment can be found as follows:

- Page 4, lines 15-19, make it clear that the RT step is performed using an oligonucleotide, and is not limited to a specific sequence;
- Page 4, line 24 to page 5, line 6 make it clear that the PCR step is performed using selected primers that bind to the template, and is not limited to primers of specific sequence; furthermore, page 5 makes it clear that the primers named in the application are merely preferred;
- Page 5 line 8 ([0018]) indicates "Preferred oligonucleotide primers..." (as opposed to critical primers) includes those removed from claim 1.

- Page 7, lines 1-4 ([00025]) make it clear that the detection step is performed using a probe sequence capable of hybridizing with the target sequence, and is not limited to probes of specific sequence.

Step (b) has also been amended to relate to a thermostable enzyme *per se* (rather than merely the exemplary enzyme *Tth*). Step (b) of Claim 1 as filed indicates that the use of *Tth* enzyme is an exemplary but not essential feature of the method by use of the language "such as the *Tth* DNA polymer use."

Step (c) has been amended to relate to the step of "detecting" the amplified cDNA by hybridization with one or more probe polynucleotides. The revised claim element is consistent with U.S. practice. Basis can be found, for example, on page 7, lines 1-4. Page 22, lines 1-23, make it clear that the method can be performed using one or more probe polynucleotide. The preferred polynucleotide Seq. ID's have been removed to render the claim more consistent with the specification which indicates the probes and primers are merely "Preferred," at page 13, line 1 ([0054]) and page 13 line 15 ([0055]).

The remaining amendments to Claim 1 have been made to further improve the clarity of that claim and basis can be found, for example, in original Claim 1 as filed.

Claim 2

Claim 2 has been amended to relate to a thermostable enzymes *per se* (rather than *Tth*). Step (b) of Claim 1 as filed (discussed above) indicates that the use of *Tth* is a preferred but not essential feature of the method.

The remaining amendments to Claim 2 have been made to further improve the clarity of that claim and basis can be found in Claim 2 as filed.

Claims 3-10

The amendments to Claims 3-10 have been made to further improve the clarity of those claims and basis can be found in Claims 3-10 respectively of the application as filed.

Claim 11

New Claim 11 relates to a method of extracting bacteria or fungus RNA by centrifiltration, for which basis can be found in step (a) of Claim 1 as filed.

Claim 12

New Claim 12 relates to a method wherein steps (b) and (c) (that is, the amplification and detection steps) are performed simultaneously. Basis can be found on page 7, lines 1-4.

Claim 13

New Claim 13 relates to a method wherein the thermostable enzyme is Tth DNA polymerase, for which basis can be found in step (b) of Claim 1 as filed.

Claim 14

New Claim 14 relates to a method wherein the polynucleotide primers comprise:

- (i) A primer or primers for the RT step. Page 4, lines 15-19, make it clear that the RT step is performed using an oligonucleotide, and is not limited to a specific sequence. Claim 1 as filed makes it clear that up to five oligonucleotides can be used for the RT step.
- (ii) Primers for the PCR step. Page 4, line 24 to page 5, line 6, make it clear that the PCR step is performed using selected primers that bind to the template, and is not limited to primers of specific sequence.
- (iii) A probe or probes for the detection step. Page 7, lines 1-4 make it clear that the detection step is performed using a probe sequence capable of hybridizing with the target sequence, and is not limited to probes of specific sequence. Claim 1 as filed makes it clear that up to nine probes can be used for the detection step.

Claim 15

New Claim 15 relates to a method in which the RT primers are selected from the group consisting of SEQ ID NOs: 2, 4, 6, 8 and 10. Basis can be found in step (b) of Claim 1 as filed.

Claim 16

New Claim 16 relates to a method in which the PCR primers are selected from the group consisting of SEQ ID NOs: 1-10. Basis can be found in step (c) of Claim 1 as filed and on page 5, lines 8-19.

Claim 17

New Claim 17 relates to a method in which the probes are selected from the group consisting of SEQ ID NOs: 11-19. Basis can be found in step (c) of Claim 1 as filed.

Claim 18

New Claim 18 relates to a method in which the polynucleotide probe further comprises a non-radioactive label. Basis can be found, for example, on page 7, lines 6-7.

Claim 19

New Claim 19 relates to a method in which the non-radioactive label is a fluoroscein. Basis can be found, for example, on page 7, lines 6-7.

Claim 20

New Claim 20 relates to a kit for determining the presence of bacteria or fungus-yeast RNA in a sample suspected of containing said bacteria or fungus-yeast comprising a thermostable enzyme and polynucleotide primers for the RT, PCR and detection steps.

Claim 1 as filed relates to a kit and a method in which those reagents are used, and therefore provides basis. Additional basis for those features can be found as described above in relation to amended Claim 1.

Claims 21 and 22

New Claim 21 relates to a kit further comprising centrifiltration membranes and/or DEAE resin. New Claim 22 relates to a kit further comprising DNase.

Claim 1 as filed (in particular, step (a)) relates to a kit and a method in which those reagents are used, and therefore provides basis. Additional basis for those features can be found as described above in relation to amended Claim 1.

Claims 23-25

New Claim 23 relates to a kit wherein the RT primers selected from the group consisting of SEQ ID NOs: 2, 4, 6, 8 and 10.

New Claim 24 relates to a kit wherein the PCR primers selected from the group consisting of SEQ ID NOs: 1-10.

New Claim 25 relates to a kit wherein the probes selected from the group consisting of SEQ ID NOs: 11-19.

Claim 1 as filed relates to a kit and a method in which those reagents are used, and therefore provides basis.

Claim 26

New Claim 26 relates to a kit wherein the thermostable enzyme is *Tth*.

Claim 1 as filed relates to a kit and a method in which those reagents are used, and therefore provides the basis. Step (b) of Claim 1 as filed indicates that the use of *Tth* is a preferred but not essential feature of the method.

Claim 27

New Claim 27 relates to a kit for performing the method of any of Claims 1-19.

As discussed above, the method of Claims 1-19 has basis in the application as filed. Claim 1 as filed relates to a kit and a method and therefore provides basis.

Claim 28

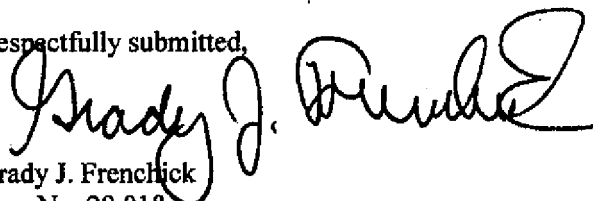
New claim 28 relates to a method for determining the presence of bacteria or fungus-yeast ribonucleic acid (RNA) in a sample. Basis can be found, for example, on page 4, lines 16-18 and page 5, lines 23-27.

Claim 29

New claim 29 relates to a method for determining the presence of bacteria or fungus yeast in a single tube. Basis can be found, for example, on page 7, lines 20-21.

The undersigned would be pleased to provide the Office with a substitute specification and/or a "clean" listing of the claims incorporating all of the changes made herein if that would make the examination proceed more smoothly. Please feel free to contact the undersigned if a replacement specification is desired.

Respectfully submitted,



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